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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,561	10/22/2001	Yoshio Jo	763-29	3304

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/01/2003

/0

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,561

Applicant(s)

JO ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, and petition for extension of time, all received on 13 January 2003. Receipt is acknowledged of the applicant's supplemental amendment, received on 09 April 2003.

Claim Objections

The objection to Claims 1-33, set forth in the previous office action, is rendered moot with the cancellation of those claims, and the introduction of new Claims 34-66.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 20 and 23 under 35 U.S.C. 112, second paragraph, as being indefinite is rendered moot with the cancellation of those claims, and the introduction of new Claims 34-66.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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The rejection of Claims 1 and 2 under 35 U.S.C. 102(e) as being anticipated by Soe *et al.* is rendered moot with the cancellation of those claims, and the introduction of new Claims 34-66.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-20, 23, and 29 under 35 U.S.C. 103(a) is rendered moot with the cancellation of those claims, and the introduction of new Claims 34-66.

Response to Arguments

Applicant's arguments with respect to cancelled Claims 1-33 and new Claims 34-66 have been considered but are moot in view of the new ground(s) of rejection.

Claims 34-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soe *et al.* (European Patent Application No. EP 0 956 869 A2) in view of Columbo *et al.* (U.S. Patent No. 4,340,731), Edwardson *et al.*, and Sugitachi *et al.* (U.S. Patent No. 4,265,233)

The EP 0 956 869 reference, published on 17 November 1999, is qualified as prior art, and will be hereafter referred to as Soe II, and contains an equivalent disclosure of the previous Soe *et al.* reference, U.S. Patent No. 6,200,587 B1, which will be hereafter referred to as Soe I.

The Soe II reference discloses a tissue sealant that comprises carboxymethyl cellulose, with a degree of etherification of preferably 0.5% to 1.5% and most preferably 0.6% to 0.8%

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(See Sections [0016] to [0017]). The sealant preferably further comprises enzymes such as thrombin, and proteins, which include fibrinogen and coagulation factor XIII. All components of the tissue sealant are biodegradable (See Sections [0015] and [0029]). A method of preparing the tissue sealant is disclosed (See Section [0039]).

The Soe II reference does not disclose the chemical bonding of proteins to cellulosic fibers through treatment with carbodiimide, nor does the reference disclose a process for the etherification of low-substituted cellulose fibers, nor does it teach a tissue sealant in the form of a fabric.

The Columbo *et al.* patent teaches a process for etherification of cellulose fibers into soluble carboxymethyl cellulose. The fibers are treated with a solution of sodium hydroxide and further treated with a monochloro acetic acid solution to form carboxymethyl cellulose with a degree of substitution equal to 0.8, and then dried. (See Column 6, Example 3).

The Edwardson *et al.* patent teaches a fibrin composition useful as a surgical sealant to provide hemostasis (See Abstract). The patent discloses that a thrombin-like enzyme may be immobilized on a support through various activation chemistries, including carbodiimide groups. Suitable supports for immobilization include cellulose and cellulose derivatives (See Column 8, Line 63 to Column 9, Line 35).

The Sugitachi *et al.* patent discloses materials for wound healing having Factor XIII and thrombin affixed to it (See Abstract; and Column 3; Lines 18-40). The material further comprises a structure which may take various forms, including cotton, non-woven fabrics, woven fabrics, knitted fabrics, twisted yarns, knitting yarns, bandages, and burn dressings, as well as absorbable materials. Natural polymers may be used to make up these structures,

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including cellulose, carboxymethyl cellulose, and methyl cellulose (See Column 1, Line 39 to Column 2, Line 4). Examples are disclosed where surgical gauze was treated and then imparted with Factor XIII and thrombin (See Examples 1 and 2). The material is described as being useful for protecting a wound site and promoting the formation of fibrin for long periods of time (See Column 8, Lines 55-68).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the references of the prior art into the object of the rejected claims. Edwardson *et al.* provides a motivation, disclosing that immobilization of a thrombin-like enzyme can prevent contamination of the composition (See Edwardson *et al.*, Column 8, Lines 57-62). The Soe II patent states that the use of low-substituted carboxymethylcellulose is preferred for the disclosed invention. Therefore, one of ordinary skill in the art would seek to find methods of producing a low-substituted cellulose ether in order to carry out the best mode of the invention described in the Soe II patent. The Columbo *et al.* patent discloses such methods of production. From there, further treatment of the material with carbodiimide according to Edwardson *et al.* may be carried out for the reasons described above. One of ordinary skill in the art would be motivated to combine the disclosure of Sugitachi *et al.* with that of Soe II so as to provide a suitable vehicle for substances such as Factor XIII and thrombin that is also capable of protecting a wound site. As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior

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art.” In this case, both the Soe II and Sugitachi *et al.* references deal with wound-treating compositions that may comprise carboxymethyl cellulose, thrombin, and Factor XIII. With the combined disclosure of the prior art, it becomes obvious to one of ordinary skill in the art that carboxymethyl cellulose, as a vehicle for substances such as thrombin, fibrinogen, and Factor XIII, can take various forms, including the sealant of Soe II, the fibers of Columbo *et al.*, and the fabrics as disclosed in Sugitachi *et al.* Regarding Claims 36-40, 42-47, and 52, it is the position of the examiner that the patentability of these composition claims does not depend on the method of production. The burden therefore shifts to the examiner to show an unobvious difference of the invention of these claims over the prior art. See MPEP § 2113. It is the position of the examiner that process variables including process times, such as that disclosed in Claim 62, may be optimized by one of ordinary skill in the art to suit various purposes, and is not considered to be critical by the examiner. Likewise, claim limitations drawn to how the proteins are imparted to the carboxymethyl cellulose, the step of pulverizing the treated fibers, the production of a fiber array having a specific thickness, or the formation of gauze through a particular process step on the treated fibers, as embodied in Claims 54, 55, 57-61, 65, and 66, are not considered by the examiner to be critical in the claimed production of a wound-healing fiber, or the function of such a fiber beyond what would be in the purview of one of ordinary skill in the art. The examiner shifts the burden onto the applicant to show the inventive criticality of these claims in the production of a wound-healing fiber. Thus, the instantly claimed invention is *prima facie* obvious.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjoh
April 25, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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